REMARKS

Claims 60 to 74 are pending in the application. No claims are amended or canceled herein. Claims 69 to 74 are newly added. No new matter is added.

Applicants believe that no fee is required for this submission. However, if a fee is required, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 23-3050. The Commissioner is also hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to Deposit Account 23-3050.

Claims 61 to 63 are objected to as allegedly being of improper dependent form for failing to limit the subject matter of a previous claim. Applicants respectfully disagree. Claim 60, from which claims 61 to 63 depend, recites that the device provides *at least one* of four recited features. Thus, a device meeting the other claim limitations and providing any one of the four recited features would be within the scope of the claim. Claims 61 and 62, however, are directed to those devices that provide the particular feature recited in the dependent claim (although such devices may also provide any or all of the three additional features recited in claim 60). Similarly, claim 63 differs from claim 60 by reciting that the device provides the *two* recited features (although such devices may also provide either or both of the two additional features recited in claim 60). Given these differences in the claims' respective scope, Applicants submit that claims 61 to 63 are in proper dependent form, and respectfully request that the rejection be withdrawn.

Claims 60 to 68 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,368,658 to Schwarz et al. ("the Schwarz Patent"). Applicants respectfully traverse this rejection. Applicants' claims recite drug delivery devices that comprise an intraluminal stent having a biocompatible, non-erodible polymeric coating having from 3 μg to 13 μg per millimeter of stent length of rapamycin (or a macrocyclic triene analog thereof that binds FKB12) incorporated therein. Independent claim 60 (the only independent claim) further recites that the device provides at least one of the following features:

an in-stent volume obstruction at 12 months following implantation in a human of less than 20%, as measured by intravascular ultrasound;

an in-stent volume obstruction at 6 months following implantation in a human of less than 20%, as measured by intravascular ultrasound;

an in-stent late loss at 12 months following implantation in a human of less than .8 mm, as measured by quantitative coronary angiography; or

an in-stent late loss at 6 months following implantation in a human of less than .9 mm, as measured by quantitative coronary angiography.

The Schwarz Patent is directed to methods and apparatus for coating medical devices and the devices thereby produced. *See* Abstract. Although the patent indicates that the devices may include stents coated with a polymeric mixture that contains an active ingredient such as rapamycin, no examples of a stent having a biocompatible, non-erodible polymeric coating containing rapamycin are provided. To the extent the reference indicates that rapamycin may be used, it is silent regarding the amount of rapamycin that should be included. Thus, the reference fails to teach or suggest a coated stent containing from 3 μg to 13 μg per millimeter of stent length of rapamycin (or a macrocyclic triene analog thereof that binds FKB12), as recited in claim independent 60. Since the reference does not describe at least this element of the claims, the reference fails to anticipate the claimed inventions. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986) (anticipation exists only when the cited reference discloses all of the elements, features, or limitations of the claimed invention).

The Office Action also contends that the Schwarz Patent describes devices that would inherently display the features recited in claims 60 to 63. The Office Action, however, fails to establish that any of these are inherent in the Schwarz Patent disclosure.

A particular claim element may be found to be inherently described in a prior art reference only when it is the natural or necessary result flowing from the teaching or practice of the prior art. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (anticipation by inherency may be found if the disclosure of the prior art is sufficient to show that the natural result flowing from the operation as taught in the prior art would result in the claimed product); *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (a finding of anticipation by inherency requires a showing that the missing element

is necessarily present in the single prior art reference). As stated in M.P.E.P. § 2112, the fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). To establish inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Thus, to establish that the Schwarz Patent inherently anticipates Applicants' claims, the burden is on the Patent Office to identify exactly which device described in the patent would necessarily possess the features recited in such claims. Not only does the Office Action fail to identify such a device, but the Schwarz Patent does not describe any specific devices having a coating that contains rapamycin or an analog thereof, and does not provide any specificity regarding how much rapamycin should be used, with which polymer, in what percentages, at what thickness, with or withour a barrier layer, etc., to provide a device that could provide an in-stent late loss or in-stent volume obstruction as recited in the pending claims. Indeed, the Schwarz Patent itself teaches that the release rate of drugs from polymeric coatings is dependent on a variety of factors, such as the particular polymer structure and formulation, the diffusion coefficient of the matrix, the solvent composition, the ratio of drug to polymer, potential chemical reactions and interactions between drug and polymer, the thickness of the drug adhesion layers and any barrier layers, the process parameters used to prepare the device, etc. *See* Schwarz Patent, col. 7, lines 3 to 20.

Accordingly, one of ordinary skill in the art would have no way of knowing whether any disclosed device containing the recited elements would possess the missing characteristics, and indeed, whether the in-stent late loss or in-stent volume obstruction parameters recited in the claims would even be achievable. Applicants therefore further respectfully submit that the claimed invention is not obvious in view of the Schwarz Patent, as well.

Additionally, Applicants wish to advise the Examiner that claims in a related application having a similar structure have previously been allowed. Specifically, the

Examiner's attention is directed to U.S. Patent No. 7,300,662 ("the '662 Patent"), where such claims were allowed after a Pre-Appeal Brief Conference. Although the Schwarz Patent was not before the Examiner in that case, it is merely cululative to art that was of record, and Applicants respectfully submit that the instant claims are likewise allowable. In view of the foregoing, Applicants respectfully request that the rejection over the Schwarz patent be withdrawn.

If the Examiner considers the instant claims and those issued in the '662 Patent to be directed to obvious variants, and the instant claims to be otherwise in condition for allowance, the favor of a telephone call to Applicants' undersigned representative is requested, so that a Terminal Disclaimer may be promptly filed to expeditiously move this application to allowance.

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